PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Donald L. MORTON *et al.*

Serial No.: 07/431,533

Filed: November 3, 1989

For: URINARY TUJMOR ASSOCIATED ANTIGEN, ANTIGENIC SUBUNITS AND METHODS OF DETECTION

Group Art Unit: 18013

Examiner: H. Sidberry

Atty. Dkt.: CADL:002/PAR

CERTIFICATION OF MAILING UNDER 37 C.F.R. §1.8

DATE OF DEPOSIT April 26, 1996

I hereby certify that this paper or fee is being deposited with the United States Postal Service under 37 C.F.R. 1.8 on the date indicated above and is addressed to Assistant Commissioner for Patents, Washington, D.C. 20231.

Steven L. Highlander

DECLARATION OF RALPH A. REISFELD UNDER 37 C.F.R. §1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

I, Ralph A. Reisfeld, declare that:

1. I am Head of the Department of Molecular Immunology at the Scripps Institute, La Jolla, CA. I have held this position for 26 years. A copy of my curriculum vitae is attached.

2. I have reviewed the abstract of Euhus *et al.*, 24th Annual Meeting of the American Society of Clinical Oncology Proceedings, May 22-24, 1988, and the claims pending in the above-captioned application. It is my understanding that the examiner in charge of the above-captioned application has alleged that the Euhus abstract anticipates or renders obvious the subject matter of the instant application.

3. Although it is true that the Euhus abstract describes an antigen designated U-TAA, which is the subject matter of the instant claims, the abstract does not enable the isolation and purification of U-TAA, since it clearly lacks the information necessary to accomplish this task. Specifically, the Euhus abstract only identifies U-TAA as existing in IgG and IgM fractions in the serum of some melanoma patients, provides its molecular mass and the fact that it contains at least four subunits of varying molecular mass. It does not, however, provide any information on the details or operating parameters of U-TAA isolation. Key conditions such as the proper pH or ionic strength under which isolation was conducted are missing, as are the migration distances or retention times for gel or column purification. Without this information, the Euhus abstract definitely lacks the necessary, detailed information to reproducibly isolate and purify U-TAA. Without such detailed information, the antigenic compositions set forth in the instant claims could not be predictably generated.

4. Therefore, based on my 40 years of experience in the isolation, purification and characterization of biological products similar to U-TAA, those of skill in the art would not have

held a reasonable expectation of success in reproducing the work described in the Euhus abstract, based solely on that disclosure.

5. I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the U.S. Code and that such willful, false statements may jeopardize the validity of this application or any patent issued thereon.

3/29/96
Date

Ralph A. Reisfeld, Ph.D.